## IN THE UNITED STATES DESIGNATED/ELECTED OFFICE

International Application No.: PCT/EP2004/006944

International Filing Date: June 28, 2004

U.S. Serial No.: 10/562,200

Deposit Date U.S. Nat'l Phase: December 23, 2005

Priority Date(s) Claimed: June 26, 2003

Applicant(s): Rudolf MOSER et al.

Title: STABLE PHARMACEUTICAL COMPOSITIONS OF 5,10-METHYLENE

**TETRAHYDROFOLATE** 

## INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.56, 1.97 and 1.98

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

## Timing and Fees

$\boxtimes$		37 C.F.R. § 1.97(b), no fee or statement is required for filing this information sure statement is filed:
		within three months of the filing date of a national application other than a CPA under § 1.53(d);
		within three months of the actual filing date of the national phase of a PCT application; OR
	$\boxtimes$	before the mailing of a first substantive office action (including after filing of an RCE).
		37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods ied in 37 C.F.R. § 1.97(b), but before the mailing date of:
		a final rejection under 37 C.F.R. 1.113; termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR a notice of allowance under 37 C.F.R. § 1.311; and

		is acco	mpanied by:
			the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR
			a check covering the fee of \$180.00 under 37 C.F.R. § 1.17(p).
			R. § 1.97(d), this information disclosure statement is filed after the mailing lowing actions which have not been withdrawn:
		a final	action under 37 C.F.R. § 1.113;
		termin	ation of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2);
		OR a r	notice of allowance under 37 C.F.R. § 1.311;
	AND i	s filed o	on or before payment of the issue fee; AND is accompanied by:
			tement as specified in 37 C.F.R. § 1.97(e) as set forth below, and the fee of 00 under 37 C.F.R. § 1.17(p).
Staten	nents Ui	nder 37	C.F.R. 1.97(e)
			Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or
			No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned attorney after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing date of the information disclosure statement.
Cited	Materia	<u>ls</u>	
		ancest	s of materials listed but not attached were cited in benefit (35 U.S.C. § 120) or application Serial No, on Form 892 by the Examiner and/or Form by the applicant; see 37 C.F.R. § 1.98(d).
	$\boxtimes$	_	s of materials listed but not attached were cited in an international search dated <u>December 30, 2004</u> .
	$\boxtimes$	Not re	quired by 37 CFR § 1.98.
		Copie	s of the materials listed are attached (except for the foregoing).

Non-Englis	sh Language References
	An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).
$\boxtimes$	A foreign-language search report from a foreign patent office is provided, and pertinent parts are translated substantively below:
	<ul> <li>X = document of particular relevance when it is taken alone</li> <li>Y = document of particular relevance when it is combined with another such document</li> <li>A = document defining the general state of the art</li> <li>O = non-written disclosure</li> <li>P = intercalated document</li> <li>T = document cited to understand the theory or principle underlying the</li> </ul>
	invention  E = patent document which has the benefit of a date earlier than the filing date and which was published only on or after this filing date  D = cited in the application  L = cited for another reason  & = publication of member of same patent family
$\boxtimes$	Translation of other relevant information on foreign search report
	In the search report, "Seite" means page, "Seiten" means pages, "Verbindunger der Formel" means Figure of formula, "Beispele" means examples, and "das ganze Dokument" means the entire document, "Spalte" means column, "Zeile' means line, "Abbildungen" means claims, "Anspruch" means example, "Zusammenfassung" means summary, and "Tabelle" means table, and "Tabellen' means tables "in der Anmeldung erwaehnt" means cited in the application, "Schema" means scheme, "und" means and, "Absatz" means break, "Abildung' means figure.
Other Infor	<u>mation</u>
	Fees Due (If Any): heck for \$ covering the fee identified above is attached.
_	ase charge to Deposit Account No. 13-3402 \$ for the fee identified above.
rie	ase charge to Deposit Account No. 13-3402 \$ for the fee identified above.

The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account #13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,

Anthony J Zelano, Reg. No. 27,969

Attorney for Applicants

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
Arlington Courthouse Plaza l
2200 Clarendon Blvd. Suite 1400
Arlington, Virginia 22201
Telephone: (703) 243-6333
Facsimile: (703) 243-6410

Attorney Docket No.: EPROV-0024

Date: November 8, 2006

AJZ/lvt

K:\eprov\24\Information Disclosure Statement.doc

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute	for form 1449A/P1	то		Complete if Known			
				Application Number	10/562,200		
INFO	RMATION	1 DISC	CLOSURE	Filing Date	December 23, 2005		
STAT	FEMENT E	BY AP	PLICANT	First Named Inventor	Rudolf MOSER et al.		
				Group Art Unit	To Be Assigned .		
	(use as many st	heets as r	necessary)	Examiner Name	To Be Assigned		
Sheet	1	of	2	Attorney Docket Number	EPROV-0024		

		U.S. P	ATENT DOCUMENTS	
Cite No.¹	U.S. Patent Docu	ment Kind Code <sup>2</sup> (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document  MM-DD-YYYY
A1	5,997,915	Α	Bailey et al.	07/12/1999
A2	6,613,767	B1	Nijkerk et al.	09/02/2003
A3	4,931,441	Α	Lawrence Richard P	06/05/1990
A4	5,434,087	Α	Beggs Michael J. et al.	07/18/1995
	A1 A2 A3	Cite No.' Number  A1 5,997,915  A2 6,613,767  A3 4,931,441	U.S. Patent Document           Kind Code² (if known)           A1         5,997,915         A           A2         6,613,767         B1           A3         4,931,441         A	Cite No.¹         Number         Kind Code² (if known)         Name of Patentee or Applicant of Cited Document           A1         5,997,915         A         Bailey et al.           A2         6,613,767         B1         Nijkerk et al.           A3         4,931,441         A         Lawrence Richard P

		F	oreign Patent Docu	ment		Date of Publication of	Pages, Columns, Lines, Where Relevant	
Examiner Initials*	Cite No.1	Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> ( <i>if known</i> )	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY	Passages or Relevant Figures Appear	T*
7C.S./	B1	wo	97/27764	Α	Ayling June et al.	08/07/1997		A1
7C.S./	B2	wo	95/26963	A	Pharmachemi BV	10/12/1995		A2

	· · · · · · · · · · · · · · · · · · ·			_
Examiner Signature	/Christopher Stone/	Date Considered	01/14/2008	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached. Number refers to English language corresponding family member.

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO Complete if Known **Application Number** 10/562,200 INFORMATION DISCLOSURE Filing Date December 23, 2005 STATEMENT BY APPLICANT First Named Inventor Rudolf MOSER et al. Group Art Unit To Be Assigned (use as many sheets as necessary) Examiner Name To Be Assigned Sheet of Attorney Docket Number EPROV-0024

Examiner Initials* Cite No.* Colonial Serial, symposium, catalog, etc.), date, page (s), volume-issue number(s), publisher, etty and/or country where publis ODIN ELISABETH ET AL., Chemical Stability And Human Plasma Pharmacokinetics of Reduced Folates, Cancer Investigation, 1998, pages 447-455, Vol. 16, No. 7.	Saller OF
initials * Cite No.' journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where publis /C.S./ ODIN ELISABETH ET AL., Chemical Stability And Human Plasma Pharmacokinetics of	
C4   OBIN ELIONE IN E., ONDINION OLDSING THE HEALTH NEW COMMONION OF THE PARTY NEW COMMONION OF THE PA	ed. T²
	-
	-
	+
	+
	_
	+
	_
	-

|--|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.